VENAFLOW® *Elite*

Operator's Manual

Prophylaxis for Deep Vein Thrombosis for use in a clinical setting or in the home

AIRCAST®

Table of Contents

Design Philosophy 2
Function 2
Intended Use/Indications 3
Contraindications 3
Warnings and Precautions 3
Latex Information 3

General System Information and Application
Pump Features 4
Symbol Definitions 5
Pump Set-Up 6
Cuff Application 7
Pump Operation 8
Single Leg Operation 8
Patient Compliance Counter Reset 8

System Alarms
Alarm Reset 8
S Mode Operation 8
Tube Alarm 9
Compliance Alarm 10
Call For Service Alarm 10

Battery Information and Operation
Battery Operation 10
Battery Charging Instructions 10
Lithium-Ion Battery Maintenance Guidelines 11
Low Battery Alarm 13
Installing or Replacing the Battery 13

Replacement Kit Instructions
Instructions for Installing/Removing/Replacing the Power Cord 14
Telescoping Bed Hanger Replacement 14
Instructions for Replacing Fuses 14

Cleaning Instructions 15
Disposal 15
Warranty 15
Optional Tube Alarm Verification Test 15
Ordering Information 16
Specifications 17
Customer Care Contact Information 17

Design Philosophy

Pneumatic compression is a clinically proven modality for minimizing the risks associated with deep vein thrombosis.[1] The Aircast VenaFlow Elite System leverages the same clinically proven technology as the existing VenaFlow offering, but is presented in a low profile, light-weight design. VenaFlow Elite combines two proven technologies, rapid inflation and graduated sequential compression, to accelerate venous velocity and enhance fibrinolysis. This unique combination makes VenaFlow the only technology platform on the market that mimics ambulation.[2] Additionally, VenaFlow Elite incorporates asymmetric compression for the superior emptying of veins.[3] The breathable and comfortable VenaFlow Elite calf, foot and thigh cuffs enhance the patient experience, assist in increasing compliance and are compatible with one universal pump.

Function

Standard Operation (rapid inflation): The VenaFlow Elite system defaults to a rapid inflation mode. Once powered on, the system begins the compression cycle and inflates the cuffs one leg at a time, alternating between the two legs every 30 seconds. First the distal aircell inflates rapidly within less than 0.5 seconds, then the proximal aircell follows. The distal pressure peaks at approximately 73 mmhg ±15% and the proximal pressure peaks at approximately 63 mmhg ±15%. These pressures then settle at 45mmhg ±10% and after 6 seconds, the cuff deflates. In 54 seconds, the inflation cycle begins again. An icon will appear on the graphical display signalling when the inflation cycle is in progress. (See 'Pump Features' section) Pressure and the inflate/deflate cycle are automatic and an alarm will be activated if the system is not functioning properly. (See 'System Alarms' section).

S Mode Operation (slow inflation): The user has an option to select the S mode button to switch to a slower inflation mode. After selection, both cuffs begin to inflate simultaneously once every 60 seconds. The inflation cycle is approximately 10 seconds long. The aircells inflate to a peak pressure of 45mmhg ±10%. In 50 seconds, the inflation cycle begins again. In S mode, pressures are automatic and alarms function normally.

1. Labropoulos N, OH D.S, Golts, E, et al: Improved Venous Return By Elliptical, Sequential and Seamless Air-cell Compression. Loyola University Medical Center, January 2003.
2. Whitelaw G, Oladipo O, Shah BP, et al: Evaluation of Pneumatic Compression Devices. Boston Orthopedics, March 2001.
3. Kamm R: Unsteady Venous Blood Flow Resulting From Different Modes of External Compression Cambridge, MIT, 1996

VENAFLOW® Elite

Intended Use/Indications

The VenaFlow Elite System is an intermittent pneumatic compression device that is intended as a prophylaxis for deep vein thrombosis (DVT) in a clinical setting or in the home. The VenaFlow Elite System is designed to be used only with VenaFlow Elite cuffs.

Contraindications

The VenaFlow Elite System should not be used by persons with known or suspected deep vein thrombosis, severe congestive heart failure, pulmonary edema, thrombophlebitis, severe arteriosclerosis, or active infection. Do not use on extremities which are not sensitive to pain, where cuff will interfere with gangrene, on patients with vein ligation or recent skin grafts, or extreme deformity of the leg. Do not use the VenaFlow Elite System where increased venous or lymphatic return is undesirable.

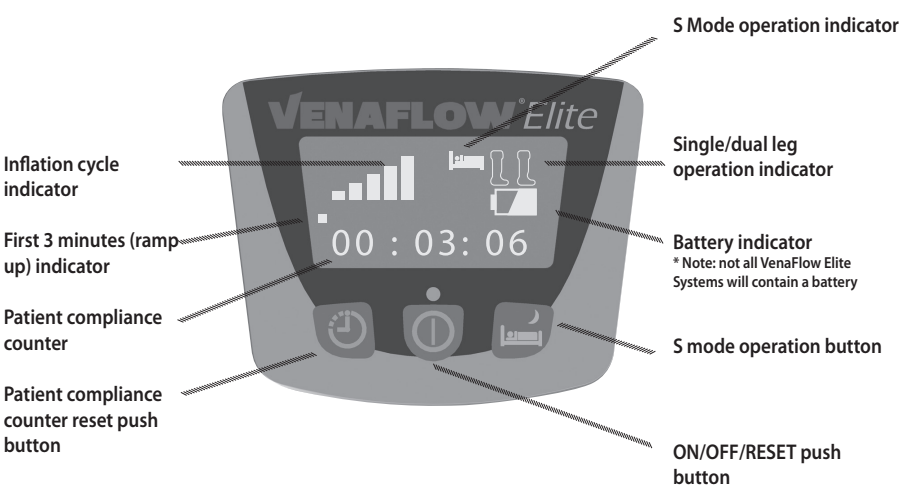
Warning and Precautions

- The VenaFlow Elite cuffs are designed for single patient use only.
- Risk of explosion if used in the presence of flammable anaesthetics.
- The equipment or system should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.
- Medical Electrical Equipment needs special precautions regarding EMC. Portable and Mobile RF Communications Equipment can be affected by other Medical Electrical Devices.
- Cuffs used in combination with warming devices may cause skin irritation. Regularly check for patient comfort, compliance and skin irritation.
- Special attention should be given to those patients with neuropathies or tissue viability problems (i.e. diabetes, arterial or venous insufficiencies).
- To prevent extremity compartment syndrome, special attention should be given to patients who are positioned in the supine lithotomy position for extended lengths of time. This includes patients with or without compression cuffs.
- If you experience pain, swelling, sensation changes or any unusual reactions while using this device, consult your medical professional immediately.
- Foot cuffs are only for use in standard rapid inflation mode.
- Ingress of water or liquids could result in unpredictable failures.
- Inspect equipment for obvious damage prior to use.
- Do not walk with tubing connected to cuffs.
- The device should never be opened by anyone other than a trained technician.
- Use of device outside of all recommended specifications could result in unpredictable failures.

Latex Information

All components of the VenaFlow Elite System are latex-free. All VenaFlow Elite cuffs are latex free and may be placed directly against the skin or over a light compression dressing.

Pump Features


S Mode operation indicator
Inflation cycle indicator
Single/dual leg operation indicator
First 3 minutes (ramp up) indicator
Battery indicator
* Note: not all VenaFlow Elite Systems will contain a battery
Patient compliance counter
S mode operation button
Patient compliance counter reset push button
ON/OFF/RESET push button
00 : 03: 06

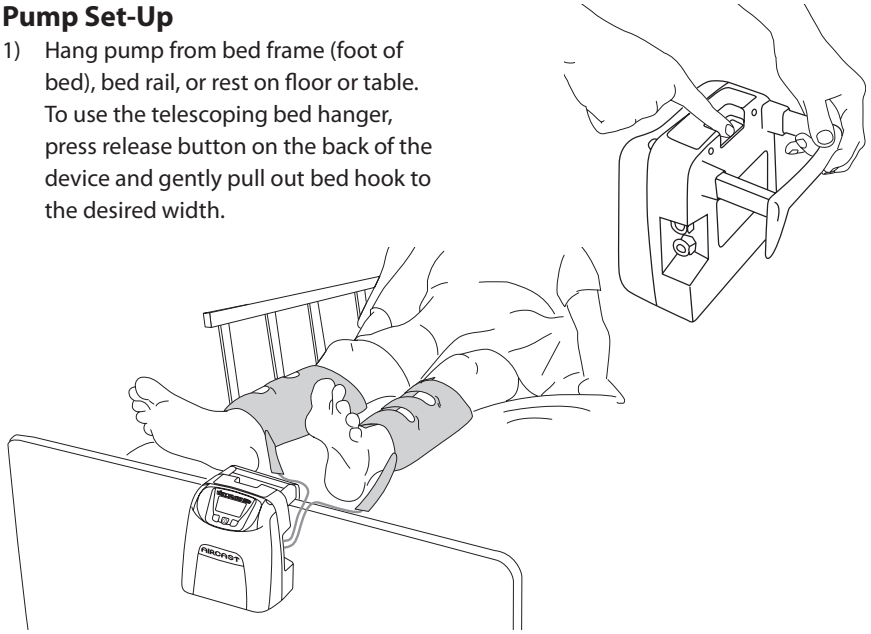
VENAFLOW® Elite

Symbol Definitions

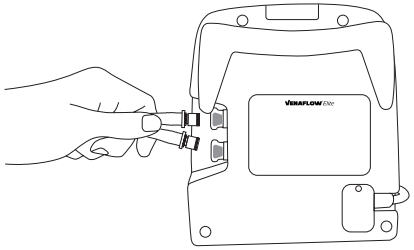
- Power on/off button and alarm reset
- Compliance monitor reset
- Tube alarm
- Call for service
- Inflation cycle indication (Bars indicate cuffs are inflating)
- See VenaFlow Elite System operator's manual
- Safety classification: Class 1 BF
- 250V 2A IEC FA 5X20MM
- Battery
- Separate collection for electrical and electronic equipment. Remove and dispose of batteries in accordance with local or national requirements.
- S Mode operation
- Lock mode
- Dual calf/thigh
- Single calf/thigh
- Dual foot
- Single foot
- C Visual only compliance alarm enabled
- $\overline{C}$ Visual and audio compliance alarm enabled

Pump Set-Up

1) Hang pump from bed frame (foot of bed), bed rail, or rest on floor or table. To use the telescoping bed hanger, press release button on the back of the device and gently pull out bed hook to the desired width.



2) Connect tube assembly to the pump. Make sure tubing connectors lock securely into pump connectors.

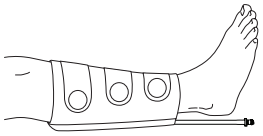


3) Plug in the power cord to electrical outlet.

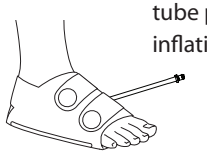
Cuff Application

The VenaFlow Elite System will automatically detect the cuff that is attached to the device and apply appropriate pressures. You must attach the cuffs prior to powering on the device.

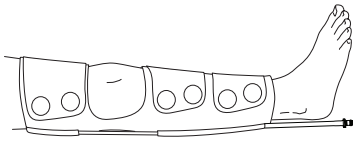
1) **Calf cuff** – Apply cuff with the tube pointed toward the foot. The aircell may be placed either on the back, side or front of the leg. It doesn't matter where the aircell sits on the leg, it will perform the same.



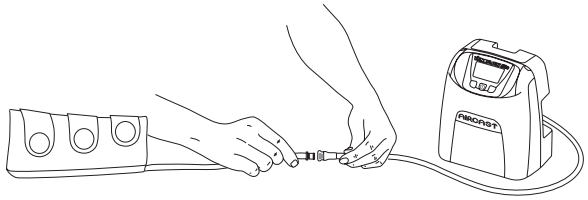
Foot cuff – Apply cuff with the aircell centered on bottom of foot and with the tube pointed to the left. Foot cuffs are only for use in standard rapid inflation mode.



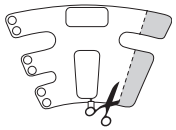
Thigh cuff – Apply cuff with the distal and proximal aircells centered on either the back, side or front of the calf and thigh with the tube pointed toward the foot. It doesn't matter where the aircell sits on the leg, it will perform the same.



2) Connect cuffs to the tubing that is attached to the pump.



For varied patient sizes, trim calf and thigh cuffs as needed for proper fit.



Be sure to secure cuff straps snug but not tight. Once again, when using the calf cuff and thigh cuff, rotation of the aircell on the leg does not affect performance of the system.

Pump Operation

1) To turn the device on, press ⏻. The graphical display, green pump indicator lights and green light above ⏻ button will turn on.
2) Once device is powered on, system will immediately enter cuff detection mode which means the system will be detecting whether or not there are cuffs attached. Display will read "Detecting Cuffs" and will display percentage of detection complete. Once it reaches 100%, the display will then transition to the standard display screen.
3) Any changes to cuff configuration requires that the device be powered off and restarted in order to detect the new configuration.
4) To turn the device off, press ⏻. The graphical display, green pump indicator lights and green light above ⏻ button will turn off.
5) To shut down the power completely, disconnect the power plug by removing it from the AC socket.

Single Leg Operation

1) Cuffs should be attached prior to powering on the device. Once powered on, the device will automatically detect if one or two cuffs are attached.
2) Any changes to cuff configuration requires that the device be powered off and restarted in order to detect the new configuration.
3) Either port may be used for single leg operation. The system will automatically detect which one is in use.
4) Single and dual leg operation are available in both standard rapid mode and S mode operation.

Patient Compliance Counter Reset

To reset the patient compliance counter, press ⏱ for 1 second and release. The hours, minutes and seconds will reset.

Alarm Reset

To reset any alarm, press the ⏻ button and take steps to correct the alarm if necessary. Pressing the button does not fix the alarm but silences it until the problem is fixed. If you wish to turn the device completely off, you must press the power button once to silence alarm and a second time to power down the device.

S Mode Operation

When powered on, the VenaFlow Elite System will default to standard rapid inflation mode. If a slower inflation is desired, select the S mode operation button. Once selected, both cuffs will inflate simultaneously once per minute. Both cuffs will inflate and compress for a total of 10 seconds. While in S mode the icon will appear in the top center of the graphical display. The device will remain in S mode until user presses the S mode operation button again. This button allows user to toggle between standard rapid inflation mode and S mode.

Locking the System in Standard Rapid or S Mode

You have the ability to lock the system in either standard rapid mode or S mode. Once a mode is locked, it will stay in that mode regardless of powering the device on or off. Once locked, it is not possible to toggle modes until the system is unlocked.

To lock the system in standard rapid inflation mode: First make sure the device is in standard rapid inflation mode. The S mode icon should NOT appear on the display. Next, press and hold the S mode button for no less than 5 seconds. After 5 seconds, a lock will appear at the top center of the display. This lock icon indicates that the system is locked in standard rapid mode.

To lock in S mode: First select S mode and make sure the S mode icon appears at the top center of the display. Press and hold the S mode button again for no less than 5 seconds. After 5 seconds, a lock will appear next to the S mode icon at the top center of the display. This lock icon next to the S mode icon indicates that the system is locked in S mode.

To unlock either mode: Press and hold the S mode button for no less than 5 seconds. After 5 seconds, the lock icon will disappear.

Tube Alarm

1) If one or both tubes has a kink or leak, after 4-6 minutes this symbol △ and the text "CHECK TUBES" will alternate on the graphical display, an audible alarm will sound and the pump indicator lights on the side of the system will flash red.
2) If a tube alarm occurs, reset alarm and then ensure that the tube connections are secure and that the tubing is kink-free. Check pump connectors and tubing/cuff connectors for cracks or damage. Check cuffs for damage as well.
3) If alarm occurs again, replace cuffs and tubing altogether.

Enabling Compliance Alarm

A compliance alarm can be enabled on the device as an option. To enable compliance feature, complete the following steps:

1) Start with the system powered off.
2) Press and hold the S mode operation button and while holding, press the power button. The graphical display screen will go blank with no backlight.
3) Press the S mode operation button.
4) Select button underneath **'Change'**.
5) Select button underneath **'Other'**.
6) Select button under **'No alarm'**.

Continued on next page

7) Select the button under **'Done'** to set the new configuration. The change is complete and the system is ready to operate. A "C" will appear on the display indicating that the compliance alarm is enabled.

Compliance Alarm

1) If the cuffs are removed from the patient while the device is still functioning and the cuffs are not reapplied after 15 minutes, a visual alarm or visual and audio alarm (depending on your selection) will flash and the graphical display will read "COMPLIANCE ALARM". Additionally, the pump indicator lights on the side of the system will flash red.
2) Reset alarm first, and then reapply cuffs. You must reapply the cuffs within 9-15 minutes after resetting the alarm in order to prevent another compliance alarm from occurring.
3) If cuffs are reapplied without resetting the alarm, the compliance alarm will automatically reset after 9-15 minutes

Call For Service Alarm

1) If one of the system's critical components is not working properly, the Call For Service alarm symbol will appear on the graphical display and it will alternate with the text "CALL FOR SERVICE". Additionally, the pump indicator lights on the side of the system will flash red.
2) If Call For Service alarm occurs, unplug the device and call DJO Technical support at 800-336-6569 option 1, option 3 for further instructions.

Battery Operation

The VenaFlow Elite System is available in a battery configuration for an additional charge. When the battery-installed system is powered on, a battery icon will appear on the right side of the graphical display beneath the leg icons and a sticker appears on the case. If the system does not have a battery installed, then there will be no battery icon on the graphical display at all. When the system with battery is unplugged and powered on, the system will automatically switch to battery power.
The battery must be charged before use. Once a system has been configured to run with a battery, it must always have a battery installed. Otherwise a 'LOW BATTERY' alarm will continuously occur. See 'Specifications' section for battery pack information.

Battery Charging Instructions

1) To charge the battery, simply plug in the system to an electrical outlet either while the system is on and functioning, or when it is powered off. The system will begin charging immediately after being plugged in.
2) The VenaFlow Elite System with a fully charged battery will last for approximately 2 hours. It takes an estimated 2 hours to fully charge the battery when the unit is off. When the unit is on, it takes an estimated 4 hours to charge the battery.

VENAFLOW® Elite

Lithium-Ion Battery Maintenance Guidelines

Overview

Do not leave batteries unused for extended periods of time because Lithium-Ion batteries continue to slowly discharge (self-discharge) when not in use or while in storage. Routinely check the battery's charge status. The product Operator's manual includes information on how to check battery status as well as battery charging instructions. When a battery has been unused for 6 months, check the charge status and charge or send the system back to DJO for battery replacement.

The typical estimated life of a Lithium-Ion battery is about two to three years or 300 to 500 charge cycles, whichever occurs first. One charge cycle is a period of use from fully charged, to fully discharged, and fully recharged again. For batteries that do not run through complete charge cycles, there is a two to three year life expectancy. The intended operating temperature of the device is between 0 and 50 °C.

Rechargeable Lithium-Ion batteries have a limited life and will gradually lose their capacity to hold a charge. This loss of capacity (aging) is irreversible. As the battery loses capacity, the length of time it will power the product (run time) decreases.

Battery Maintenance

You should routinely check the battery's charge status. Carefully monitor batteries that are approaching the end of their estimated life. Consider shipping the device back to DJO to replace the battery if you note either of the following conditions:

1. The battery run time drops below about 80% of the original run time.
2. The battery charge time increases significantly.

If a battery is stored or otherwise unused for an extended period, be sure to follow the storage instructions in this document. If you do not follow the instructions, and the battery has no charge remaining when you check it, consider it to be damaged. Do not attempt to recharge it or to use it. Send the system back to DJO for replacement.

Charging

Always follow the charging instructions provided in your Operator's manual.

Storage

Charge or discharge the battery to approximately 50% of capacity before storage. Charge the battery to approximately 50% of capacity at least once every six months. The battery is best stored at 20±5 °C. For periods of less than 1 month, the battery can be stored between -20~45 °C.

NOTE: The battery self-discharges during storage. Higher temperatures (above 20 °C or 68 °F) reduce the battery storage life.

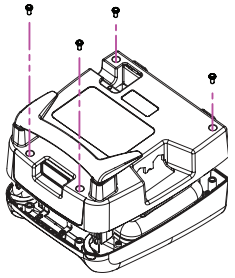
Handling Precautions

- Do not disassemble, crush, or puncture a battery.
- Do not short the external contacts on a battery.
- Do not dispose of a battery in fire or water.
- Do not expose a battery to temperatures above 60 °C (140 °F).
- Keep the battery away from children.
- Avoid exposing the battery to excessive shock or vibration.
- Do not use a damaged battery.
- If a battery pack has leaking fluids, do not touch any fluids.
- Properly dispose of a leaking battery pack.
- In case of eye contact with fluid, do not rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.

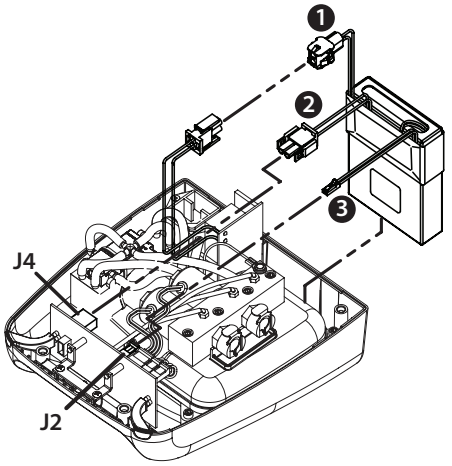
Low Battery Alarm

1) When there is approximately 15 minutes of charge left in the battery, an audible alarm will beep 3 times every minute. When there is less than approximately 5 minutes of charge left, a consistent beep will sound and a larger version of the battery icon will appear on the graphical display and it will alternate with the text "LOW BATTERY".
2) When either battery alarm occurs, immediately plug device in to electrical outlet to begin replenishing the charge.
3) If the device is not plugged in during the alarm period, the device will shut down and will fail to power on again until the device is plugged in again.

Installing or Replacing the Battery



1) Remove power cord. Refer to the **'Instructions for installing/removing/replacing the power cord'** section.
2) Remove back cover of device by removing 4 screws using TORX (star) T20 driver.
3) Remove power supply connector from board connector J4.
4) Install battery into the device below the reservoir.
5) Attach power supply connector to battery connector #1.
6) Attach battery connector #2 to J4 connector on board.
7) Attach battery connector #3 to J2 connector on board.
8) Close back cover of device and fasten screws.
9) Reinstall the power cord and power cord cover per previous instructions.
10) Plug in the system.
11) Hold down single/dual leg operation button and then press the power button to turn on the system. LCD back light will turn on, with blank LCD.
12) Release the single/dual leg operation button.
13) Press and release counter reset button.
14) Turn off the system by pressing the power button. Battery will be configured at this point.
15) Turn on the system. After the cuff detection cycle, the system should display a battery icon on the right hand side of the LCD.
16) Leave the device plugged in for at least 4 hours to allow battery to charge. The battery will charge whether the system is turned on or off.

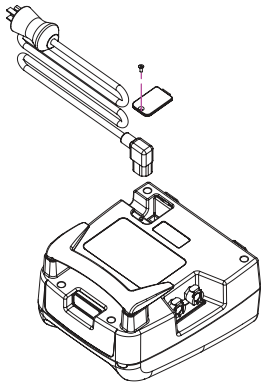


Replacement Kit Instructions

Replacement kits may be ordered through customer care.

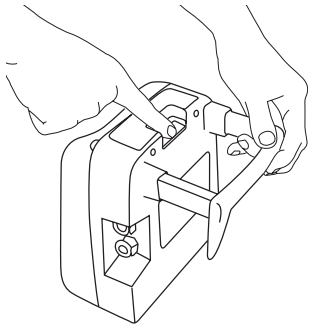
Instructions for Installing/Removing/ Replacing the Power Cord

1) Make sure system is powered off and unplugged.
2) Remove the screw retaining the power cord cover using a 1/16" hex driver.
3) Remove the power cord cover.
4) Remove the power cord.
5) Install new power cord and reassemble power cord cover.



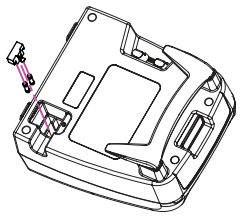
Telescoping Bed Hanger Replacement

1) The telescoping bed hanger piece can be removed and replaced if necessary.
2) To replace the bed hanger, hold down release button on the back of the system and firmly pull bed hanger out of the body of the system.
3) Discard the broken or ineffective hanger. To install the new bed hanger, slide the new hanger back into the body of the device and set at desired length.



Instructions for Replacing Fuses

1) Remove the power cord. Refer to the **'Instructions for installing/removing/replacing the power cord'** section.
2) Remove fuse holder from power entry module.
3) Remove fuses from fuse holder.
4) Replace any blown fuses with 250V, 2A, IEC fast acting 5X20mm fuses.
5) Reassemble fuse holder and replace power cord per previous instructions.



Cleaning Instructions

Both the pump case and the tube assembly can be cleaned with a mild soap solution, antiseptic or disinfectant wipes. DJO tested numerous disinfectants on the device and found no adverse effects using isopropyl alcohol and hydrogen peroxide (Oxivir Tb). According to the results, it is advised to avoid using Dimethyl benzyl ammonium chloride or Dimethyl ethylbenzyl ammonium chloride (Tec-Surf II), or solutions containing chlorine. Apply using a dampened cloth or wipes. Do not submerge the device in any liquid.

Disposal

All contaminated product or accessories should be disposed of properly according to hospital policy and/or state law.

Warranty

For consigned systems: DJO, LLC will repair or replace all or part of the 30B-S and 30B-SB systems for material or workmanship defects for the life of the customer contract. Warranty and maintenance terms are specified for each consignment contract.

For purchased systems: DJO, LLC will repair or replace all or part of the 30B-S or 30B-SB systems for material or workmanship defects for 3 years from the date of sale. For disposable cuffs, tubing and battery pack purchases: DJO, LLC will repair or replace all or part of the cuffs, tube units and battery packs for material or workmanship defects, not including normal depreciation of battery life or charge capacity, for a period of six months from the date of sale.

Optional Tube Alarm Verification Test

The Tube Alarm Verification Test is provided for facility verification purposes only and is not required prior to use.

Attach tube assembly to pump and connect power cord to electrical outlet. Simulate a kinked tube situation by folding the tube over onto itself once and holding it for 4-6 minutes. The second cycle after the simulated kink should activate an audible alarm and this symbol ⚠ will appear with "CHECK TUBES" on the graphical display and the pump indicator lights on the side of the system will flash red.

Ordering Information (Reference separate IFU for each accessory)

Systems:

Part #	Description
30B-S	VenaFlow Elite System with S Mode
30B-SB	VenaFlow Elite System with S Mode & Battery
30BI-S	VenaFlow Elite System, International with S Mode
30BI-SB	VenaFlow Elite System, International with S Mode & Battery

Accessories:

Part #	Description	Qty	Maximum Calf Circumference
3040	VenaFlow Elite Calf Cuff	Pair	19″
3042	VenaFlow Elite XL Calf Cuff	Pair	22″
3043	VenaFlow Elite Bariatric Calf Cuff	Pair	30″
3045	VenaFlow Elite Thigh Cuff	Pair	One size fits all
3046	VenaFlow Elite Foot Cuff	Pair	One size fits all
3050	VenaFlow Elite Foam Calf Cuff	Pair	19″
3008	Tube Assembly, 5.5'	Each	
3008XL	Tube Assembly, 8.5'	Each	
3008XXL	Tube Assembly, 10.5'	Each	
3008XXXL	Tube Assembly, 12.5'	Each	

System Replacement Parts

Part #	Description
3070	Power Cord (U.S.), Hospital Grade
3071	Bed Hanger
3072	Tube Attachment Tag
3073	Fuse
3074	Battery Pack

VENAFLOW® Elite

Specifications

Size: 7.6″ x 8.5″ x 4.6″
Weight: no battery: 4 lbs. with battery: 4.75 lbs.
Power input: 100-240~, 50-60 Hz, 200 – 500 mA
Cord: Hospital grade, 15 ft
Standards: IEC 60601-1, IEC 60601-1-2
TUV Device Classification: Class 1 BF
Inflation mode: rapid inflation and graduated, sequential compression
Bed hanger: accommodates up to 3.5″
Battery: Li-ion polymer 11.1V, 4250 mAh
Fuse: 250V 2A IEC FA 5X20MM

Storage

Storage/Transportation Temperature: 0° C (32° F) to 50° C (122° F).

Operating Conditions

Operating Temperatures: 0° C (32° F) to 50° C (122° F)
Relative Humidity: 30% to 70%
Atmospheric Pressure: 650 mmhg to 790 mmhg

Customer Care Contact Information

Service: 800-336-6569 press option 1, then option 3
Technical support: 800-336-6569 ext 5566

DJO, LLC
A DJO Global Company
1430 Decision Street
Vista, CA 92081-8553 • USA
T 800.336.6569 • F 800.936.6569
DJOglobal.com

Rx Only

30B119 Rev A